#8
JRP
3/19/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: William E. Yelle

Serial No.: 10/046,464 Group Art Unit: 1614

Filed: October 19, 2001 Examiner: Cook, R.

Title: HYDROXYLANSOPRAZOLE METHODS

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, January 21, 2003.

Philip E. Hansen
Agent for Applicant
Reg. No. 32,700

Date of Signature: January 21, 2003

To: Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE UNDER 37 C.F.R. 1.111

Dear Sir:

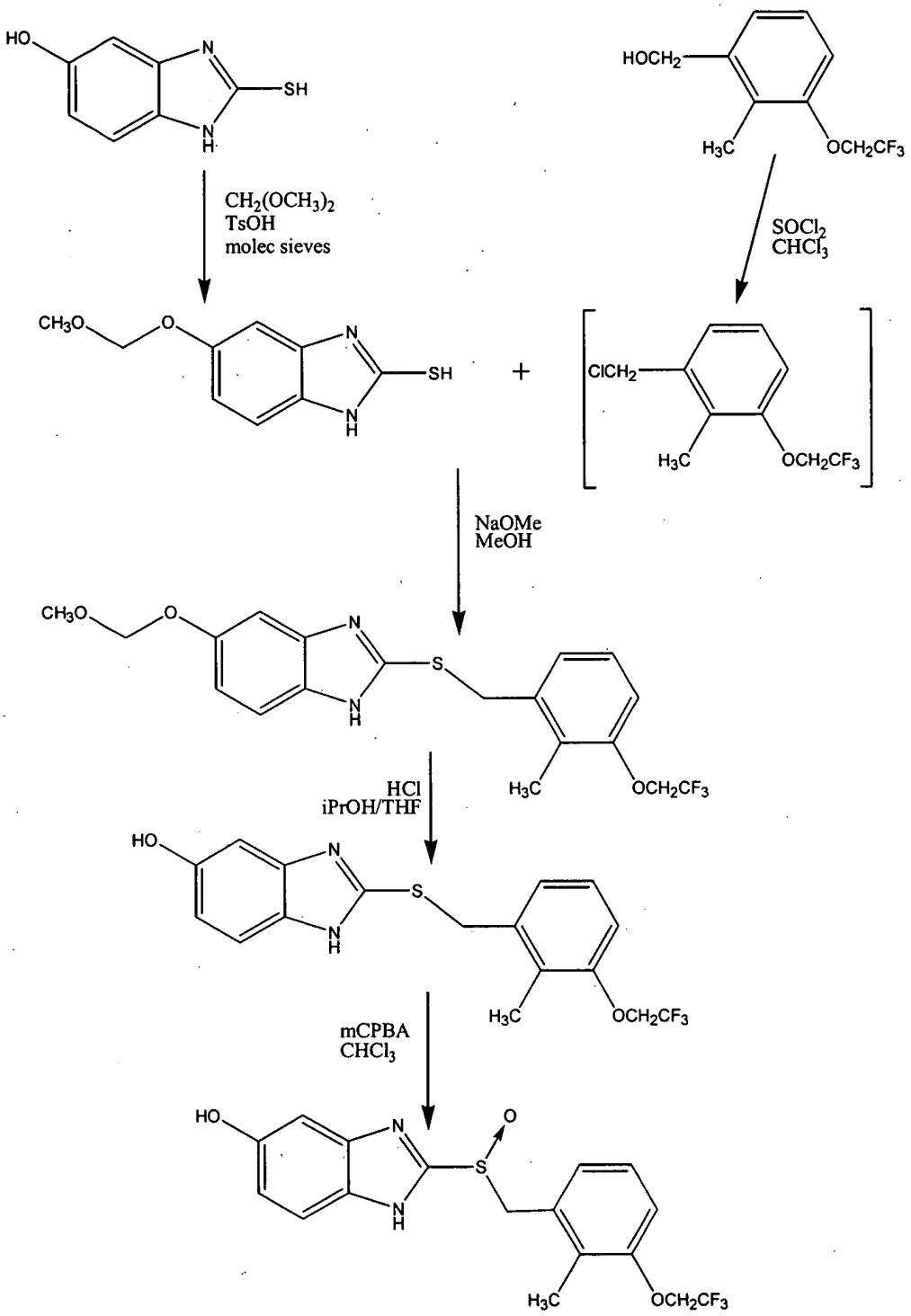
This is in response to the Office Action of July 30, 2002. In light of a Request for three month extension and fee therefore enclosed herewith, response is due by January 30, 2003. This response is therefore timely filed.

Claims 1-15 were present in the application as filed. In response to a request to elect species, applicant elected the treatment of ulcers, which is read upon by claims 1, 2 and 7-15. Claims 1-15 are pending in the application, but, having found generic claim 1 unallowable, the examiner has withdrawn claims 3-6 from consideration.

In the Office Action of July 30, 2002, claims 1,2 and 7-15 were rejected under 35 U.S.C. §112, first paragraph. 35 USC §112, first paragraph, states:

> "The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

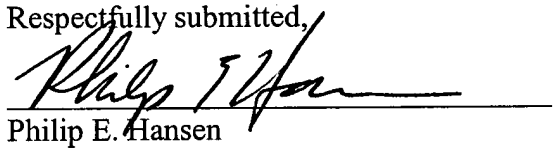
The Office Action makes clear that this is an "enablement" rejection, i.e. the Office questions whether the applicant has described the invention, and the process of making and using it, so that the person of skill could carry out the invention. The invention (as defined by claim 1) is a method of treating ulcers in humans by administering a therapeutic amount of hydroxylansoprazole. The specification (page 4) describes a method for synthesizing hydroxylansoprazole:


HO
N
SH
N
H
$CH_2(OCH_3)_2$
TsOH
molec sieves
$HOCH_2$
H_3C
OCH_2CF_3
$SOCl_2$
$CHCl_3$
CH_3O
O
N
SH
N
H
+
$ClCH_2$
H_3C
OCH_2CF_3
NaOMe
MeOH
CH_3O
O
N
S
N
H
H_3C
OCH_2CF_3
HCl
iPrOH/THF
HO
N
S
N
H
H_3C
OCH_2CF_3
mCPBA
$CHCl_3$
HO
N
O
S
N
H
H_3C
OCH_2CF_3

It also describes two formulation processes (page 12-13) for making tablets of 200mg or 250mg, which may be enterically coated by a third process, also described. The specification discloses that a daily human dose ("therapeutic amount" in the language of the claim) is preferably about 500 mg to 1000mg, i.e. two to five tablets per day. Applicant respectfully submits that any person of skill would know how to make and use the invention from this disclosure. Reconsideration and withdrawal of the rejection are requested.

There being no other outstanding issues, the application is believed in condition for allowance, and such is respectfully requested.

Respectfully submitted,



Philip E. Hansen
Agent for Applicants
Reg. No. 32,700

Dated: January 21, 2003

Address for Correspondence:
Heslin Rothenberg Farley & Mesiti P.C.
5 Columbia Circle
Albany, New York 12203
Telephone: (518) 452-5600
Facsimile: (518) 452-5579